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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,564	01/27/2000	PASCAL CLAUDE MICHEL LOUVEL	P1047/20008	6103

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EXAMINER

EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/402,564

Applicant(s)

LOUVEL ET AL.

Examiner

Nabila G. Ebrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 10, and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Applicant's remarks and amendments to the claims dated 2/12/07 is acknowledged.

Status of Claims

Claims 8, 10, and 11 are pending in the application.

Claim 11 is new.

Status of Office Action: Final.

Claim Rejections - 35 USC § 112

In view of Applicant's arguments and amendments to the claims, the rejection of claim 8 and 10 under 35 USC §112 is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 8, and 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. WO 96/14058 in view of Martin et al. US 5811186.

Oshlack et al (WO 96/14058) disclosed an apparatus (Fig 9/17), an extrusion system for making particles comprising extruder drive motor, controls cooling and temperature controls, feed hopper, a die; pelletizer which contains rotating cutter, rollers, fixed knife and the like (page 21, lines 29-30 bridging to page 22, lines 1-14). Oshlack disclosed the method of manufacturing particulates (page 23, lines 10 and page 33, lines 15-28 to page 34, lines 1-5) and forming hard gelatin capsules formulation wherein the temperature employed is 83 degrees (page 23, lines 17, 105 degrees, page 24, lines 21-23); and wherein the extruded strands (filaments) or strands are congealed and cut into desired size (page 23, lines 29). Oshlack disclosed the use of the thermoplastic polymer like acrylic polymer, Eudragit (page 24, lines 19-22) or ethylcellulose (examples 1, 9, and 10) and a plasticizer like diethylphthalate (example 7). Oshlack also disclosed that the extruded multiparticulate system can be in the form of spheroids (page 17, line 29) and that the extruded multiparticulates can be any geometrical shape within a size range; e.g. beads, microspheres, seeds, pellets (page 18, lines 5-9).

Oshlack also disclosed the same step disclosed in instant claim 10 in the same order of steps a) to e) in the instant application. The steps included:

a) selecting a drug, hydrophobic material and binder with any further excipients.

- b) blending.
- c) feeding the extruder with the blend.
- d) extruding the resultant mass.
- e) transport to pelletizer (chopping).

Oshlack is deficient in disclosing the maturing step.

Martin discloses melt-extruded thermoplastic filaments or fibers. A thermoplastic polymer used is selected from a group of polymers like polyurethanes, and acrylic polymers (col. 17, lines 26+). Martin teaches that surprisingly, heat aging (maturing) was found to improve the blend's flex-fatigue resistance (col. 19, lines 16-19).

Accordingly, it would have been obvious to one of ordinary skills in the art to prepare particulates of an active agent using melt extrusion technique as disclosed by Oshlack to provide a sustained release active substance (page 6 lines 1-5) and combine it with Martin's disclosure to age the blend and adjust the temperature and period of aging according to the active substance included in the blend, the motivation would be the disclosure of Martin that the heat aging was found to improve the blend's flex-fatigue resistance. Therefore, this invention as a whole would have been prima facie obvious to one of ordinary skill at the time the invention was made.

Response to Arguments

2. Applicant's arguments filed 2/12/07 have been fully considered but they are not persuasive. Applicant argues that:

- a. Oshlack's Fig. 9 does not depict the cutters of claim 8. It is the specific limitations of the cutters of claim 8, such as the recessed second face and strip of a

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specified width, which enable the apparatus of the invention to provide spheroidal particles from the chopping step without any additional spheroidal shaping step.

To respond: The disclosure is not limited to the Fig. 9. The figure may show an embodiment but not all and every embodiment. Noted that Oshlack's invention could achieve the manufacture of a multiparticulate including speroids made of melt extruded material using an extrusion system for making particles comprising extruder drive motor, temperature and cooling controls, feed hopper, a die, pelletizer which contains rotating cutter, rollers, fixed knife and the like which are the same parts used in the apparatus disclosed in the instant claims.

b. Martin et al. is non-analogous art, which is not in the same field as the present invention and is not pertinent to the problems addressed by the claimed invention.

To respond: Martin teaches the same melt-extruded thermoplastic filaments or fibers. Though Martin is not concerned with spheronization, it is noted that the thermoplastic polymer used is selected from a group of polymers like acrylic polymers as disclosed in the current application. Martin teaches that surprisingly, heat aging (maturing) was found to improve the blend's flex-fatigue resistance. Accordingly, a man of ordinary skill in the art would navigate through the pertinent art to ensure improving the melt-extruded thermoplastic products.

C. Applicant argues that: Flex-fatigue resistance is not a property relevant to particles for making pharmaceutical tablets, and certainly suggests nothing regarding the release of active principle from particles.

To respond: pharmaceutical products and tablets are related to flex-flex fatigue resistance (if necessary see US 5073381 which discloses a pharmaceutical tablet containing a drug for ingestion and teaches that a key property for the invention include, flex fatigue resistance).

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

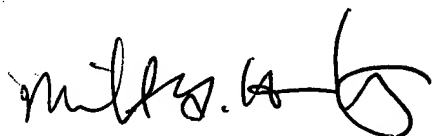
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim

4/27/07


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER